REMARKS

A. Status of the Claims

Prior to the submission of this paper, claims 1-28 were pending, with claims 1-17 under examination and claims 18-28 withdrawn from consideration. In this paper, Applicants have cancelled claims 2, 3, 6, 10, and 17 without prejudice or disclaimer. Following the cancellation of these claims, the claims under examination will be claims1, 4-5, 7-9, and 11-16.

Claims 1-2, 6-10, and 12-17 currently stand rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pre-Grant Publication No. 20060165730 to Porro et al., ("Porro").

Claims 1-17 currently stand rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over PCT publication no. WO 2000/10599 to Michon et al., ("Michon"), in view of PCT publication no. WO 1994/05325 to Tai et al., ("Tai") and an abstract by Hronowski et al., ("Hronowski") entitled "Abstracts of the General Meeting of the American Society for Microbiology" 93:155 (1993), XP009040462 & 93rd General Mtg. of the American Society for Microbiology; Atlanta, GA, USA; May 16-20, 1993, Issn: 1060-2011.

B. Explanation of the Amendments

Claim 1 has been amended to specify that the immunogenic conjugate comprises a "a group Y meningococcal polysaccharide fragment obtained from an O-acetyl positive group Y meningococcal polysaccharide, wherein the group Y meningococcal polysaccharide fragment has a molecular weight less than about 150 kDa

and has been O-deacetylated by at least 80%." Claim 1 further specifies that the "group Y meningococcal polysaccharide fragment" is "completely N-acetylated." Support for these claimed features is generally found throughout the specification [see, e.g., WO 2005/000347, p. 7, lines 2-6; p. 8, lines 14-21, p. 9, lines 8-13, and original claim 3].

Claims 4, 5, 7, 8, 9, and 11-16 have been amended to ensure that the claimed subject matter of dependent claims is consistent with preceding claims and to correct claim dependencies.

The specification has been amended so that the paragraph that begins on page 7, line 1 of WO 2005/000347 states that "[i]n some embodiments, the degree of de-O-acetylation is at least 80%." This statement is supported by claim 1 as originally filed and is added to the specification in accordance with MPEP § 2163.06.

Applicants respectfully submit that no new matter has been added by these amendments.

C. Applicants' Claims Are Novel Over Porro

Applicants respectfully traverse the rejection of claims 1-2, 6-10, and 12-17 under 35 U.S.C. § 102(e) for allegedly being anticipated by Porro. Briefly, Porro fails to disclose all of the elements of the claimed invention and therefore this ground of rejection should be withdrawn. See Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (stating that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.")

Claim 1, as amended, specifies that (1) the claimed "immunogenic conjugate" comprises an "a group Y meningococcal polysaccharide fragment obtained from an O-acetyl positive group Y meningococcal polysaccharide, wherein the group Y meningococcal polysaccharide fragment has a molecular weight less than about 150 kDa and has been O-deacetylated by at least 80%", and (2) the claimed "immunogenic conjugate" is "completely N-acetylated." Nowhere does Porro disclose such an O-deacetylated group Y meningococcal polysaccharide fragment. To the contrary, Porro merely reports four different ways of derivatizing an intact bacterial polysaccharide in order to introduce reactive amino groups in the carbohydrate, none of which lead to the claimed "group Y meningococcal polysaccharide fragment". First, Porro states that reductive amination may be used to attach alkyl diamine spacers to a polysaccharide at "selected regions" in which native vicinal diols have been oxidized to aldehydes by oxidizing agents such as sodium periodate. [Porro, ¶ [0024], [0025]]. Second, Porro reports that vicinal diols may be treated with lead acetate to produce vicinal aldehydes that could be subjected to reductive amination. [Porro, ¶ [0026]]. Third, Porro reports that vicinal O-acetyl groups may be "selectively and quantitatively" hydrolyzed using anhydrous hydrazine [Porro, ¶ [0027]] to produce O-deacetylated groups that can be reductively aminated. Finally, Porro states that carboxyl groups may be reacted with carbodiimide to generate reactive amino groups [Porro, ¶ [0028]]. However, none of these processes reported by Porro leads to a "group Y meningococcal polysaccharide fragment" that "has a molecular weight less than about 150 kDa." Furthermore, none of these processes produces a "group Y meningococcal polysaccharide fragment" that is "O-

deacetylated by at least 80%" but "completely N-acetylated" as recited in Applicants' claims.

For at least the foregoing reasons, claims 1-2, 6-10, and 12-17 are novel over Porro. Accordingly, Applicant respectfully requests reconsideration and withdrawal of t the rejection of claims 1-2, 6-10, and 12-17.

D. Applicants' Claims Are Patentable Over the Cited References

Applicants respectfully traverse the rejection of claims 1-17 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Michon, in view of Tai, and in further view of Hronowski. Briefly, the combination of references fails to teach or suggest all of the elements of the claimed invention. Accordingly, Applicants request that this ground of rejection be withdrawn. See, In re Royka. 490 F.2d 981, 985 (CCPA 1974) (obviousness requires a suggestion of all limitations in a claim).

As noted above, claim 1 has been amended to specify that the "immunogenic conjugate" contains an "a group Y meningococcal polysaccharide fragment obtained from an O-acetyl positive group Y meningococcal polysaccharide, wherein the group Y meningococcal polysaccharide fragment has a molecular weight less than about 150 kDa and has been O-deacetylated by at least 80%". Furthermore, claim 1 specifies that the O-deacetylated group Y meningococcal polysaccharide fragment is "completely re-N-acetylated."

The proposed combination of Michon, Tai, and Hronowski fails to teach or suggest such an O-deacetylated group Y polysaccharide fragment. For example,

Michon does not teach or suggest such a fragment because Michon requires at least some of the N-acetyl groups to be converted into N-acryloyl groups for coupling to protein:

> "[a] percentage of the N-acetyl groups removed by hydrolysis from the polysaccharide are replaced by N-acryloyl groups, which in turn, are directly coupled to protein to form the conjugate of the present invention. [Michon, p. 4, lines 20-22].

Accordingly, the polysaccharides of Michon are not "completely re-N-acetylated" as specified by the claims.

Similarly, Tai does not disclose an "O-deacetylated O-acetyl positive group Y meningococcal polysaccharide" as recited in applicant's claims. Tai reports that Group C meningococcal polysaccharide can be de-O-acetylated by treatment with base [Tai, p. 5, line 21- p. 6, line 15]. However, Tai does not teach or suggest re-N-acetylation of the Group C polysaccharide, much less a re-N-acetylated de-O-acetylated Group Y meningococcal polysaccharide as specified in applicant's claims.

Hronowski also fails to teach or suggest the claimed de-O-acetylated Group Y meningococcal polysaccharide, as Hronowski is directed to Group C meningococcal polysaccharides. Furthermore, Hronowski is silent on any process involving re-N-acetylation and does not teach or suggest any molecular weight range.

As the cited references fail to teach or suggest all of the features of the claimed invention, the rejection under 35 U.S.C. § 103(a) should be withdrawn. Accordingly, Applicants respectfully request withdrawal of all pending rejections to claims 1-17 and allowance of the case.

CONCLUSION

In view of the foregoing remarks and amendments, Applicants respectfully submit that claims 1-17 are allowable. In the event that the Examiner believes that issues exist that can be resolved by telephone conference, or that any formalities can be corrected by an Examiner's Amendment, a telephone call to the undersigned at (212) 827-4318 is respectfully requested.

Respectfully submitted,
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